



06-28-05

cew 1614.  
\$

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Rodriguez, et al.

Application No.: 10/051,662

Filing Date: January 18, 2002

Title: Prevention of Ovarian Cancer by Administration of a Vitamin D Compound

Group Art Unit: 1614

Examiner: Rebecca Cook

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. 1.97 and 1.98, and in compliance with 37 C.F.R. 1.56, the Office's attention is directed to the references listed on the attached PTO-1449 forms. A copy of each of the listed documents is enclosed.

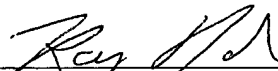
The Commissioner is hereby authorized to charge the fee of \$180 prescribed in 37 C.F.R. § 1.17(p) and any additional fees associated with the filing of this Information Disclosure Statement as indicated on the attached Credit Card Payment Form.

06/29/2005 GWORDOF1 00000104 10051662

01 FC:1806

180.00 OP

Respectfully submitted,

  
Raymond N. Nimrod  
Registration No. 31,987

Jenner & Block LLP  
One IBM Plaza  
Chicago, IL 60611  
Ph. (312) 927-5833  
Fax (312) 923-8406

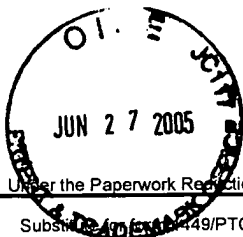
Date: June 27, 2005

**CERTIFICATE OF EXPRESS MAIL UNDER 37 CFR 1.10**

"Express Mail" Label No. EUS9535040US Date: 6/27/05  
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Va 22313-1450.

  
Signature

  
typed/printed name



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substantive Examination/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 5

**Complete if Known**

Application Number	10/051,662
Filing Date	January 18, 2002
First Named Inventor	Gustavo C. Rodriguez
Art Unit	1614
Examiner Name	Rebecca Cook
Attorney Docket Number	31140B

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 5,798,345	08/25/1998	Knutson et al.	
		US- 5,852,056	12/22/1998	Samid	
		US- 5,716,945	02/10/1998	Grue-Sorensen	
		US- 5,567,695	10/22/1996	Labrie	
		US- 5,565,439	10/15/1996	Piazza et al.	
		US- 5,545,634	08/13/1996	Labrie	
		US- 5,541,172	07/30/1996	Labrie et al.	
		US- 5,532,228	07/02/1996	Neef et al.	
		US- 5,434,146	07/18/1995	Labrie et al.	
		US- 5,362,720	11/08/1994	Labrie	
		US- 5,196,510	03/23/1993	Rodwell et al.	
		US- 5,115,096	05/19/1992	Shoyab et al.	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

**FOREIGN PATENT DOCUMENTS**

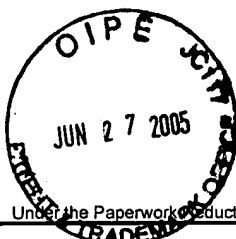
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

2

of

5

**Complete if Known**

Application Number	10/051,662
Filing Date	January 18, 2002
First Named Inventor	Gustavo C. Rodriguez
Art Unit	1614
Examiner Name	Rebecca Cook
Attorney Docket Number	31140B

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		MUSS, H.B., et al., "High-dose progestin therapy for metastatic breast cancer", Annals of Oncology 3:S15-S20 (1992)	
		VOGEL, CHARLES L., "Hormonal Approaches to Breast Cancer Treatment and Prevention: An Overview", Seminars in Oncology, Vol. 23, No. 4 Supp. 9, 2-9 (1996)	
		Locker, G.Y., "Hormonal therapy of breast cancer", Cancer Treatment Reviews 23:221-240 (1998)	
		MUSS, HYMAN B., et al., "Tamoxifen Versus High-Dose Oral Medroxyprogesterone Acetate as Initial Endocrine Therapy for Patients With Metastatic Breast Cancer: A Piedmont	
		(continued from above) "Oncology Associate Study", Journal of Clinical Oncology, Vol. 12 No. 8 (August), (1994)	
		LUNDGREN, S., "Progestins in Breast Cancer Treatment", ACTA ONCOLOGICA, Vo. 31 No. 7 709-722 (1992)	
		VINK-VAN WIJNGAARDEN, T., et al. "Inhibition of Breast Cancer Cell Growth by Combined Treatment with Vitamin D3 Analogues and Tamoxifen" Cancer Research 54:711-5717, 11/1/1994	
		CHRISTAKOS, S., "Vitamin D and Breast Cancer", Diet and Breast Cancer, Chapter 12, 115-118 (1994)	
		BEER MD, T. et al., "A Phase I trial of pulse calcitriol in patients with refractory malignancies Pulse dosing permits substantial dose escalation", Cancer Vol. 91, Issue 12	
		(Continued from above) Pages 2431-2439 (June 15, 2001)	

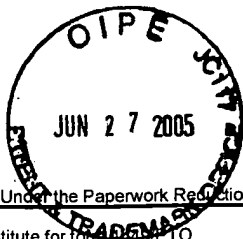
Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/051,662
		Filing Date	January 18, 2002
		First Named Inventor	Gustavo C. Rodriguez
		Art Unit	1614
		Examiner Name	Rebecca Cook
Sheet 3 of 5	Attorney Docket Number	31140B	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		GILL, P.G. et al., "Randomized comparison of the effects of tamoxifen, megestrol acetate, or tamoxifen plus megestrol acetate on treatment response and survival in patients	
		(Continued from above) with metastatic breast cancer", Annals of Oncology 741-744 (1993)	
		BOWER, M., et al., "Topical calcipotriol treatment in advanced breast cancer", The Lancet, Vol. 337 (March 23, 1991)	
		GULLIFORD, T. et al., "A phase I study of the vitamin D analogue EB 1089 in patients with advanced breast and colorectal cancer", British Journal of Cancer, 6-13, (1998)	
		KANDOUZ, M. et al., "ANTAGONISM BETWEEN ESTRADIOL AND PROGESTIN ON BCL-2 EXPRESSION IN BREAST-CANCER CELLS, Int. J. Cancer: 68, 120-125 (1996)	
		Vogel, C., "Update on the current use of hormonal therapy in advanced breast cancer", Use of hormonal therapy in advanced breast cancer, Anti-Cancer Drugs, 14:265-273 (2003)	
		BEAT, T., "Anastrozole versus progestin/tamoxifen", European Journal of Cancer 38 Supplement 6, S49-S51 (2002)	
		BURAS, R. et al., "Vitamin D receptors in breast cancer cells", Breast Cancer Research and Treatment 31:191-202, (1994)	
		LOVE-SCHIMENTI, C. et al., "Antiestrogen Potentiation of Antiproliferative Effects of Vitamin D3 Analogues in Breast Cancer Cells 1", Cancer Research 56, 2789-2794 (6/15/96)	
		Smith, D., et al., "A Phase I Trial of Calcitriol (1,25-Dihydroxycholecalciferol) in Patients with Advanced Malignancy <sup>1</sup> ", Clinical Cancer Research, Vol. 5, 1339-1345, (6/1999)	

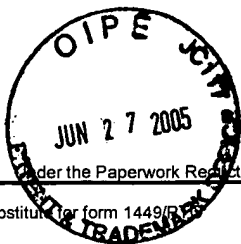
Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449 (P)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/051,662
Filing Date	January 18, 2002
First Named Inventor	Gustavo C. Rodriguez
Art Unit	1614
Examiner Name	Rebecca Cook
Attorney Docket Number	31140B

Sheet	4	of	5
-------	---	----	---

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		SPEROFF MD, L., "The Risk of Breast Cancer Associated with Oral Contraception and Hormone Replacement Therapy", Women's Health, Vol. 2, 63-74, (1992)	
		JAMES, S. et al., "Effects of a new synthetic vitamin D analogue, EB 1089, on the oestrogen-responsive growth of human breast cancer cells", Journal of Endocrinology,	
		(Continued from above) 141, 555-563, (1994)	
		MILLER, W. et al., "Anti-tumor Effects of Letrozole", Cancer Investigation, Vol. 20, Suppl. 2 pp. 15-21, (2002)	
		BLAND MD, K., et al., "Current Status of Endocrine Therapy for Advanced Breast Cancer", Ann Surg. Oncol., Vol. 6, No. 8, 4S-7S, (1999)	
		BEER, T. et al., "Beer Abstract" (2002)	
		Mathiasen, I. et al., "EB 1089, A NOVEL VITAMIN D ANALOGUE, HAS STRONG ANTIPROLIFERATIVE AND DIFFERENTIATION INDUCING EFFECTS ON CANCER CELLS", J. Steroid Biochem. Molec.	
		(Continued from above) Biol. Vol. 46, No. 3, pp. 365-371, (1993)	
		KAUFMANN, M., "A Review of Endocrine Options for the Treatment of Advanced Breast Cancer", Oncology 1997; 54 (suppl 2):2-5	
		HOLICK, M., "Evolutionary Biology and Pathology of Vitamin D", 79-83 Symposium Vitamin D, (?)	

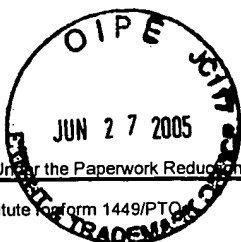
Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Sheet	5	of	5	Application Number	10/051,662
				Filing Date	January 18, 2002
				First Named Inventor	Gustavo C. Rodriguez
				Art Unit	1614
				Examiner Name	Rebecca Cook
				Attorney Docket Number	31140B

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		JENG, M-H, et al., "Estrogenic Potential of Progestins in Oral Contraceptives to Stimulate Human Breast Cancer Cell Proliferation <sup>1</sup> ", Cancer Research 52, 6539-6546, (12/1/92)	
		SHABAHANG, M. et al., "1-25 Dihydroxyvitamin D3 Receptor as a Marker of Human Colon Carcinoma Cell Line Differentiation and Growth Inhibition", Cancer Research 53, 3712-3718	
		(Continued from above) (Augst 15, 1993)	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

**Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.